II. DRAWINGS

Corrected drawings will be supplied as required in the Office Action; however, it is respectfully requested that the correction be held in abeyance pending a holding of allowable claims herein.

II. SPECIFICATION

An abstract of the disclosure on a separate sheet is appended hereto.

IV. RESPONSE TO CLAIM OBJECTIONS AND REJECTIONS

The claims specifically objected to and or rejected have been cancelled and replaced by new claims 22-52 inclusive.

The new claims have an initial predicate for "ICT" and claim 52, the only claim that includes the word "square" spells it out. None of the new claims use the word "embedded". It is believed that the new claims show the relationship between the movable conjugate of label and purified antibodies and the fixed unlabelled purified antibodies on the capture line of the test device. The new claims also identify a first zone and a second zone on the ICT device.

Originally 21 claims were presented and a fee was paid for one independent claim in excess of 3 and one claim in excess of 20. With this amendment, there are now four independent claims, i.e., retained claims 1 and 12 and new claims 22 and 43 for a total of 4. Since 4 independent claims were originally paid for (1 in excess of 3), no further fee for independent claims is submitted herewith. The total number of claims now in this

application is 36 (5 retained claims plus 31 new ones). 21 claims were originally paid for and a check to cover the $135 small entity fee for 15 additional claims is submitted herewith. A fee calculation sheet showing this is filed herewith.

RESPONSE TO 35 U.S.C.§103 REJECTIONS

The combination of Imrich *et al* with Cuatrecasas *et al* does not render the invention as presently claimed in Claims 22-52 obvious within the meaning of 35 U.S.C. §103. Imrich *et al* does not suggest any assay process in which purified antibodies are employed for the purpose of improving sensitivity and specificity of the assay but speaks only of "immunoglobulin", apparently on the premise that *any* immunoglobulin from any source will do, except in the case of *Streptococcus* A wherein "DEAE-purified Rabbit-anti-*Strep*-A" is mentioned (col. 10 lines 35-36 and 50-51). Similarly, from the way in which the Imrich *et al* disclosure treats bacterial antigens, one could also infer that Imrich *et al* is suggesting that each bacteria mentioned has only one antigen. See, e.g. claim 5 referring, *inter alia,* to "*Pseudomonas aeruginosa* antigen, *Chlamydia trachomatis* antigen, *Neisseria gonorrhae* antigen, *Legionella pneumophila* antigen..." without evincing any recognition of the probable presence of numerous antigens in each bacteria species, the likelihood that some antigens will cross-react with bacteria of other species and hence be unreliable if sought to be used in diagnosing disease, the fact the raw antibodies "purified" only with DEAE may cross react with more than one antigen and may hence may not be reliable in attempting to detect disease even when considered with clinical symptoms, etc.

Furthermore, Imrich *et al* contains no suggestion that it would be helpful to combine an assay with affinity purification of the antibodies to be used in the assay, much less a

suggestion of the manner in which Applicants have proceeded to design their own affinity purification step.

Applicants do *not*, however, contend that they originated affinity purification. Rather they contend that they devised the particular affinity purification step that requires, as a preliminary, the purification of a bacterial carbohydrate antigen so as to render it essentially protein-free followed by coupling it to an affinity purification column over which antibodies to the bacteria from which the antigen was obtained are and thereby rendered antigen-specific. Neither Cuatrecasas *et al* nor any other cited reference makes any suggestion for such an affinity purification step. Moreover Imrich *et al* and Cuatrecasas *et al,* taken singly or together, do not suggest Applicants' antigen extraction-purification process, Applicants' use of the so-purified antigen in an affinity chromatography step to purify antibodies raised against the bacteria from which the antigen was obtained and purified, or the use of the purified and now antigen specific antibodies in an assay for the crude antigen in human body fluids. Nor do any of the references suggest the high sensitivity and high specificity of the assay in detecting the crude bacterial antigen.

The further rejection of now cancelled claim 18 over Imrich *et al* in view of Cuatrecasas *et al* and in further view of Yen *et al* and Hansen *et al* is equally non-meritorious. Applicants do not contend that they invented gold labelling or that theirs is the only method of assaying for an antigen characteristic of a particular species or serogroup of a species of bacteria. With respect to Yen, the teachings are of the advantages of using magnetic gold microspheres as a label for cells in various operations.

It *is* suggested at col. 15, lines 14-16 that these magnetic gold microspheres "should also be valuable...in biochemical and immunochemical binding and agglutination assays",

but it is noted that Applicants' preferred label is colloidal gold and not magnetic gold microspheres. Moreover, Applicant's claims in reciting colloidal gold as a preferred label do so only in the context of covering a preferred mode of labelling the novel purified antibodies and their outstanding properties upon which the claims, in large measure, depend for patentability.

Insofar as the Hansen *et al* reference is concerned, it employs monoclonal antibodies which are not the same as Applicant's purified polyclonal anitbodies. It is not at all clear the Hansen *et al* reference seeks to detect the capsular antigen of *Haemophilus influenzae* type b that applicant's examples show to be addressed by applicant's assay. Moreover, in col. 6, lines 35 to 58 of Hansen *et al* it is said that what is sought to be detected is an "endotoxin" and that it is preferred that it be "captured" by two monoclonal antibodies. Even if it be *assumed* that the capsular antigen of *Haemophilus influenzae* type b that Applicants' method detects somehow corresponds to the Hansen *et al* "endotoxin"--and there is no clear basis for such an assumption-- the methodology of detection, as between Hansen *et al* and Applicants is *very different*. Applicants are clearly entitled, as is *anyone*, to a patent on a new and less cumbersome mode of achieving an old result that they have invented. Here, there is nothing in the reference to say that Applicants' result has any commonality with that disclosed by Hansen *et al*.

In the circumstances, the combination of Imrich *et al*, Cuatrecasas *et al,* Hansen *et al* and Yen *et al* is not one that suggests the subject matter of Applicants' claims or that arises from any suggestion in any one or more of these references that leads inevitably to combination with the others. Instead, these references have been combined in hindsight on a piecemeal basis springing from knowledge of Applicants' invention as disclosed.

Withdrawal of the 35U.S.C.§103 (a) rejections is accordingly believed appropriate and is urged.

CONCLUSION

It is believed that the present application is now in condition for allowance, Action to that effect is accordingly courteously requested.

Respectfully submitted,

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